

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor and Reissue Applicant: Arun Srivastava

Art Unit:

TO BE ASSIGNED

Reissue of Patent No.:

6,261,834

Examiner:

TO BE ASSIGNED

Assignee: Research Corporation Technologies, Inc.

Issued:

July 17, 2001

Reissue Application No.: TO BE ASSIGNED

For:

VECTOR FOR GENE THERAPY

Commissioner for Patents United States Patent and Trademark Office Alexandria, Virginia 22313-1450

DECLARATION IN SUPPORT OF REISSUE UNDER 37 C.F.R. §§ 1.175 and 1.63

Sir:

- I, Arun Srivastava, declare and state as follows:
- I am a U.S. citizen and reside at 7601 Dubonnet Way, Indianapolis, IN 46278. 1.
- I believe that I am the original, first and sole inventor of the subject matter 2. which is described and claimed in U.S. Patent No. 6,261,834 ("'834 patent"), granted on July 17, 2001, and for which I solicit a reissue patent.
- The '834 patent is assigned to Research Corporation Technologies, Inc., Tucson, 3. AZ.
- I have reviewed and understand the contents of the specification and claims of 4. the '834 patent. I have also reviewed and understand the contents of the Preliminary Amendment attached hereto.
- · 5. I believe that the '834 patent is partly inoperative or invalid by reason of claiming less than there was a right to claim in the patent.

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- 6. Independent claim 1 is directed to an expression vector. The structural features of the expression vector are set forth in claim 1 as comprising "two inverted terminal repeats of adeno-associated virus 2 and at least one cassette comprising a promoter capable of effecting cell-specific expression wherein said promoter is operably linked to a heterologous gene, and wherein said cassette resides between said inverted terminal repeats." The expression vector is characterized in the preamble as "for site-specific integration and cell-specific gene expression".
- 7. I believe that the invention of claim 1 of the '834 patent is properly implemented without the preamble expression "for site-specific integration and cell-specific gene expression." A principal feature provided by the '834 patent resides in the recognition that cell-specific expression of a heterologous gene can be achieved by placing such gene under control of a cell-specific promoter and between two ITR sequences of AAV. The AAV ITR sequences achieve stable integration into the host genome without causing substantial toxicity to the host cells, in contrast to the random integration of retroviral vectors. The critical structural elements of the expression vector, i.e., a cell-specific promoter, a heterologous gene and two AAV ITR repeats, are already set forth in claim 1. The preamble "for site-specific integration and cell-specific gene expression" merely describes certain mechanistic features of the recombinant AAV vector and is not necessary for the purpose of defining the expression vector. It is unclear as to whether such mechanistic features in the preamble should be read as a limitation of the expression vector of claim 1. To the extent that such mechanistic features will be read as a limitation of the expression vector of claim 1, I believe that claim 1 is too narrow and the patent claimed less than there was a right to claim in the patent.

- 8. This error of claiming less than there was a right to claim in the patent to the extent that the preamble expression is read as a limitation of the claimed expression vector, arose without any deceptive intention on my part.
- 9. To correct this error and to claim what the patentee had a right to claim, claims 1-15 are canceled and new claims 16-30 are added by way of the Preliminary Amendment.

 Claim 16, directed to an expression vector, does not contain the expression "for site-specific integration and cell-specific gene expression." Claims 17-30, which depend from claim 16, are written in the same manner as dependent claims 2-15 of the '834 patent.
- 10. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with 37 C.F.R. § 1.56.
- 11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: July 16, 2003

Arun Srivastava



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REVOCATION OF POWER OF ATTORNEY AND GRANT OF NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Sir.

The undersigned, a representative authorized to sign on behalf of the assignee owning all of the interest in this patent, hereby revokes all previous powers of attorney or authorization of agent granted in this patent before the date of execution hereof. The undersigned hereby grants its power of attorney to Kenneth L. Cage, Registration No. 26,151, McDermott, Will & Ernery 600 13th Street, N.W., Washington, D.C. 20005-3096, with full power of substitution to prosecute the reissue application and transact all business in the United States Patent and Trademark Office in connection therewith.

Please send all future correspondence concerning this application to the following address:

> Kenneth L. Cage Registration No. 26,151 McDermott, Will & Emery

600 13th Street, N.W. Washington, D.C. 20005-3096 Tel: (202) 756-8363

Date:

(Signature)

(Name) (Title) Timothy J. Reckart Senior Vice President and

General Counsel

Research Corporation Technologies, Inc.

Registration No. 33,274



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Statement Under 37 C.R.F. 3.73(b)

Sir:

- I hereby certify that Research Corporation Technologies, Inc. is the assignee of 1. the entire right, title and interest in U.S. Patent 6,261,834.
- The inventor of U.S. Patent 6,261,834, Arun Srivastava, has transferred his right, 2. title and interest in and to the subject matter of U.S. Patent 6,261,834 by Assignment dated December 11, 1992 to Research Corporation Technologies, Inc., which has been recorded in the U.S. Patent and Trademark Office on June 21, 1993, Reel/Frame No. 6634/0060.
- To my knowledge and belief, Research Corporation Technologies, Inc. has title in 3. and to U.S. Patent 6,261,834.
- I am the Senior Vice President and General Counsel of Research Corporation 4. Technologies, Inc. and I am authorized to sign this certification on behalf of Research Corporation Technologies, Inc.

5. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date:

(Signature)

(Name) (Title) Timothy J. Reckari

Senior Vice President and

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ASSENT OF ASSIGNEE TO REISSUE

Sir:

The assignee of the entire interest in U.S. Patent 6,261,834, hereby assents to the accompanying reissue application. Attached are a Statement under 37 C.R.F. 3.73(b), establishing the right of the assignee to take action in this reissue application, and a new Power of Attorney.

July 16, 200

(Signature)

(Name)

Timothy J. Reckart

(Title)

Senior Vice President and

General Counsel

Research Corporation Technologies, Inc.

PTO Registration No. 33,274